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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,290	08/21/2001	Rosana Kapeller-Libermann	MNI-186	8801

7590 09/15/2004

Intellectual Property Group  
MILLENNIUM PHARMACEUTICALS INC.  
75 SIDNEY STREET  
CAMBRIDGE, MA 02139

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/935,290

**Applicant(s)**

KAPELLER-LIBERMANN ET AL.

**Examiner**

Nashaat T. Nashed, Ph. D.

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/2/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, and 6-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The application has been amended as requested in the communication filed July 2, 2004. Accordingly, claims 3 and 5 have been canceled, and claims 4, 6, 7, and 8 have been amended.

Claims 1, 2, 4, and 6-11 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 4, and 6-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported for the reasons set forth in the prior Office action mailed January 21, 2004.

In response to the above rejection, applicants argue that the specification sets forth use of the described compositions in a method for diagnostics and identification of therapeutics for disorders including, for example metabolic disorders, and that one of ordinary skill in the art would have recognized well-established utility. They further argue that the specification as filed in conjunction with the knowledge of those skilled in the art would equip one to readily demonstrate the acyltransferase activity.

Applicants' arguments filed June 21, 2004 have been fully considered, but they are found unpersuasive. Indeed, the specification sets forth use of the described compositions in a method for diagnostics and identification of therapeutics for disorders including, for example metabolic disorders, but it has not identified a single disease or disorder, including a specific metabolic disorder, which the claimed nucleic acid or the protein product encoded by the claimed nucleic acid can be diagnosed or useful in identifying potential drugs for the treatment of said disease or disorder. The fact that the nucleic acid sequences of SEQ ID NO's: 1 and 3 and the amino acid sequence of SEQ ID NO: 2 are not previously known in the prior art, one of ordinary skill in the art would have recognized that neither the nucleic acid sequences of SEQ ID NO's: 1 and 3, or the amino acid sequence of SEQ ID NO: 2 have any well established utility. While it may be possible for one of ordinary skill in the art to demonstrate the acyltransferase activity of the protein of SEQ ID NO: 2, the application must contain an asserted specific or substantial utility at the time the application was filed. Since the application failed to identify a specific or substantial utility at the time it was filed, the claims remain rejected.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, and 6-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the nucleic acid sequence of SEQ ID NO: 1 or 3, and the protein of SEQ ID NO: 2

Claims 4, and 6-11 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office action mailed January 21, 2004.

Applicants argue that disclosure enabling for the claims as amended and assume that the rejection is based on the number of possibilities of the nucleic acid being claimed.

Applicants' arguments filed 6/21/04 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that disclosure enable the claimed invention. Applicants make no effort to explain why they consider the disclosure of the nucleic acid sequences of SEQ ID NO's: 1 and 3 which encodes the amino acid sequence of SEQ ID NO: 2 and general methods of assaying for acytransferase activity sufficient enablement for any nucleic acid sequence which is at least 95% identical to SEQ ID NO's: 1 or 3, or comprises at least 150 contiguous nucleotide of SEQ ID NO's: 1 or 3, any nucleic acid encoding a polypeptide having 95% identical to SEQ ID NO: 2, or any nucleic acid sequence comprising the coding sequence of 50 contiguous amino acid residue of SEQ ID NO: 2 having any acytransferase activity. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

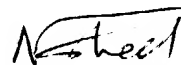
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1652